Examiner's Amendment and Comments

1. Request for continued examination (i.e., R.C.E.) under 37 C.F.R. §1.114, including the fee set forth in 37 C.F.R. §1.17(e), was filed in this application on 11 November 2007 after a Final action mailed 30 July 2007 and an Advisory Action mailed 27 November 2007. Since this application is eligible for continued examination under 37 C.F.R. §1.114, and the fee set forth in 37 C.F.R. §1.17(e) has been timely paid, the finality of the previous Office action mailed 30 July 2007 has been withdrawn pursuant to 37 C.F.R. §1.114. Submission and the R.C.E. filed 30 November 2007 have been entered. Accordingly an R.C.E. has been established and the action on R.C.E. follows.

2. The responsive amendment filed 30 November 2007 is acknowledged and entered...

General Informal Matters

3. The instant application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) has now been assigned in Art Unit 1657. To aid in correlating any papers for this application (i.e., 09/853,635) all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

Withdrawals of Rejection based on Applicant's Amendments

4. In view of remarks and amendments filed 30 November 2007 the following objections And rejections in the Office Action mailed 07 August 2007 are hereby withdrawn:

- Objections to claim 104;
- Indefiniteness rejections to Claims 114-115, 129-130 and 138 under 35 U.S.C. §112, second paragraph; and
- Obviousness rejection to claims 104, 106, 108-115, 117, 120, 124-127, 129-131 and 138-139 under 35 U.S.C. § 103 (a) as being obvious over combined teachings from Kosbab (WO 00/07607) in view of Bombardelli et al. (EP 0,6559,402) and Hersh (U.S. Patent 5,906,811).

Claims Status

5. Claims 1-103 are cancelled

6. Claims 140-149 have been added

7. Claims 104, 112, 114-115, 120, 124, 129-131, 134-135 and 137-139 have currently been amended.

8. Claims 105, 107, 116, 118 -119, 121-123, 128 and 132-133 remain withdrawn.

9. Claims 104-149 are pending.

Restriction/Election Rejoinder

10. In view of Literature search, Claims 105, 121-123 and 132-133 previously withdrawn from consideration as a result of a restriction requirement are now subject to being rejoined. As a result of rejoinder supra, Claims 105, 121-123 and 132-133 are regrouped with Claims 104, 106,108-115, 117, 120, 124-127, 129-131 and 134-149 and examined as one single invention.

11. Claims 104-106, 108-115, 117, 120-127 and 129-149 are examined on merits.

Examiner's Amendment

12. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview on 14 February 2008 with Mr. Stanislaus Aksman, Applicants' Representative.

In the Specification:

In the Brief Description of the Drawings, page 8, lines 18-24 replace the text with:

Figure 16 shows a temporal plot of "Sanitation Index" and the presence of positive results (presumptive) for *Salmonella* for beef trim produced from the carcasses sampled in Figure 15. The data

shows that the increasing carcass sanitation index (Figure 15) was correlated with a coordinate increase of trim sanitation index and the appearance of positive results (presumptive) for *Salmonella*.

Figure 17 shows a temporal plot of carcass sanitation index, showing a period of time where the index was elevated (highlighted by the dashed box). After corrective actions were taken by the plant, subsequent values of the carcass sanitation index are lowered.

In the Claims:

The following listing of claims will replace all prior versions, and listings, of claims in the instant application:

Listing of Claims:
1-103 (canceled).

104. (Previously Presented): A method of increasing collagen synthesis or lessening the decrease in collagen synthesis in the dermis comprising the oral administration to a human in need thereof of a composition comprising:

i) at least one glycosaminoglycan found in cartilage enzymatic hydrolysate, or a synthetic form of at least one glycosaminoglycan;
ii) at least one polyphenolic, hydrophilic antioxidant found in grape seed; or
synthetic form of at least one polyphenolic hydrophilic antioxidant and esters thereof; and
iii) lycopene; and
wherein the weight ratio of the at least one polyphenolic, hydrophilic antioxidant to the lycopene is about 1:1 to about 200:1 and the weight ratio of the at least one glycosaminoglycan to the at least one polyphenolic, hydrophilic antioxidant is about 1:1 to about 200:1.

105. (Rejoined): A method according to claim 104, wherein the at least one polyphenolic, hydrophilic antioxidant is obtained from a grape seed extract.

106. (Previously Presented): A method according to claim 104, wherein said at least one polyphenolic, hydrophilic antioxidant is obtained from at least one natural source.

107. (Canceled):

108. (Previously Presented): A method according to claim 104, wherein said at least one polyphenolic, hydrophilic antioxidant comprises an oligomeric procyanidol.

109. (Previously Presented): A method according to claim 104, wherein said lycopene is obtained from a tomato variety.

110. (Previously Presented): A method according to claim 104, wherein said lycopene is obtained from a tomato extract.

111. (Previously Presented): A method according to claim 104, wherein said composition, further comprises a carotenoid comprising β-carotene, γ-carotene, δ-carotene, zeaxanthin, cryptoxanthine, ~~luteine~~ lutein, xanthophyll, or a combination thereof.

112. (Previously Presented): A method according to claim 104, wherein the composition comprises said lycopene in an amount of 0.1 to 5% wt/wt.

113. (Previously Presented): A method according to claim 111, wherein the composition comprises less than 0.025% β-carotene by weight.

114. (Previously Presented): A method according to claim 104, wherein the composition comprises 0.25-15 mg of the lycopene and further comprises 2.5-100 mg of a grape seed extract.

115. (Previously Presented): A method according to claim 104 wherein said composition comprises 1-2.5 mg of the lycopene, and further comprises 5-50 mg of a grape seed extract and 50-200 mg of a cartilage enzymatic hydrolysate.

116. (Canceled):

117. (Previously Presented): A method according to 104, wherein said composition further comprises Acerola extract.

118-119. (Ccanceled)

120. (Previously Presented): A method according to claim 114, wherein said composition comprises 0.75-2.5 mg of the lycopene and 10-30 mg of the grape seed extract.

121. (Rejoined): A method according to claim 104, wherein said composition is in a form for oral administration comprising tablets, powders, granules, capsules, sachets, solutions, suspensions, tonics of syrups, or a combination thereof.

122. (Rejoined): A method according to claim 105, wherein the grape seed extract is obtained by using organic solvents.

123. (Rejoined): A method according to claim 122, wherein said grape seed extract comprises up to 25% w/w of catechin, epicatechin or gallic acid; up to 90% w/w of epicatechin dimer, trimer or tetramer, or gallates thereof, or up to 10% w/w of epicatechin pentamer, hexamer or heptamer, or gallates thereof.

124. (Previously Presented): A method according to claim 104, wherein said glycosaminoglycan is from a cartilage enzymatic hydrolysate obtained by enzymatic proteolytic cleavage of a cartilage.

125. (Previously Presented): A method according to claim 124, wherein said cartilage is selected from the group consisting of bovine cartilage, porcine cartilage, shark cartilage, squid cartilage, chicken cartilage and salmon cartilage.

126. (Previously Presented): A method according to claim 104, wherein said glycosaminoglycan is from a shark cartilage enzymatic hydrolysate obtained by enzymatic proteolytic cleavage of said shark cartilage.

127. (Previously Presented): A method according to any one of claims 104 and 124, wherein said glycosaminoglycan comprises chondroitin ester, a keratan ester, hyaluronic acid or an ester thereof, a dermatan ester, heparin or a heparan ester.

128. (Canceled):

129. (Previously Presented): A method according to claim 124, wherein the composition further comprises a cartilage enzymatic hydrolysate and a grape seed extract, and the cartilage enzymatic hydrolysate and the grape seed extract are present in a weight/weight ratio in the range of from about 5: 1 to 15:1.

130. (Previously Presented): A method according to claim 124, wherein the composition further comprises a cartilage enzymatic hydrolysate and a grape seed extract, and the cartilage enzymatic hydrolysate and the grape seed extract are present in a weight/weight ratio of about 1:2 to 2:1.

131. (Previously Presented): A method according to any one of claims 104 and 124, wherein the composition further comprises a cartilage enzymatic hydrolysate, and the cartilage enzymatic h,/drolysate and the lycopene are present in a weight/weight ratio of about 1:2 to 2:1.

132. (Rejoined): A method according to claim 122, wherein the grape seed extract is obtained by using the organic solvents, evaporating the solvents, re-dissolving a residue in water, and filtering and drying a filtrate.

133. (Rejoined): A method according to claim 122, wherein the organic solvents are selected from the group consisting of acetone, ethyl acetate and mixtures thereof.

134. ((Previously Presented) :): A method according to claim 104, wherein the weight ratio of the at least one polyphenolic, hydrophilic antioxidant to lycopene is 2:1 to 100:1.

135. (Currently amended): A method according to claim 104, wherein the weight ratio of the at least one glycosaminoglycan to the at least one polyphenolic, hydrophilic antioxidant is 2:1 to 100:1.

136. (Canceled):

137. (Currently Amended): A method according to claim 104, which includes a ~~cosmetic or prophylactic~~ treatment of skin against the signs of skin ageing, and damage resulting from exposure to UV radiation.

138. (Previously Presented): A method according to claim 127, wherein said composition comprises 1-2.5 mg of the lycopene, and further comprises 5-50 mg of a grape seed extract and 50-200 mg of a cartilage enzymatic hydrolysate.

139. (Previously Presented): A method according to claim 129, wherein said composition comprises 1-2.5 mg of the lycopene, 5-50 mg of the grape seed extract and 50- 200 mg of the cartilage enzymatic hydrolysate.

140. (Previously Presented): A method according to claim 104, wherein the weight ratio of the at least one polyphenolic, hydrophilic antioxidant to lycopene is 5:1 to 50:1.

141. (Previously Presented): A method according to claim 104, wherein the weight ratio of the at least one polyphenolic, hydrophilic antioxidant to lycopene is 5:1 to 20:1.

142. (Previously Presented): A method according to claim 104, wherein the weight ratio of the at least one polyphenolic, hydrophilic antioxidant to lycopene is 5:1 to 15:1.

143. (Previously Presented): A method according to claim 104, wherein the weight ratio of the at least one polyphenolic, hydrophilic antioxidant to lycopene is 7:1 to 12:1.

144. (Previously Presented): A method according to claim 104, wherein the weight ratio of the at least one polyphenolic, hydrophilic antioxidant to lycopene is about 10:1.

145. (Previously Presented): A method according to claim 104, wherein the weight ratio of the at least one glycosaminoglycan to the at least one polyphenolic, hydrophilic antioxidant is 5:1 to 50:1.

146. (Previously Presented): A method according to claim 104, wherein the weight ratio of the at least one glycosaminoglycan to the at least one polyphenolic, hydrophilic antioxidant is 5:1 to 20:1.

147. (Previously Presented): A method according to claim 104, wherein the weight ratio of the at least one glycosaminoglycan to the at least one polyphenolic, hydrophilic antioxidant is 5:1 to 15:1.

148. (Previously Presented): A method according to claim 104, wherein the weight ratio of the at least one glycosaminoglycan to the at least one polyphenolic, hydrophilic antioxidant is 7:1 to 12:1.

149. (Previously Presented): A method according to claim 104, wherein the weight ratio of the at least one glycosaminoglycan to the at least one polyphenolic, hydrophilic antioxidant is about 10:1.

Examiner's Reasons for Allowance

13. The following is Examiner's statement of reasons for allowance:

The closest art are:

- WO 00/07607 published 17 February 2000, inventor- Kosbab.

  Kosbab teaches cancer protective and therapeutic compositions and additionally formulae to treat osteoporosis. Kosbab also teaches stimulation or promotion of collagen maintenance and synthesis (See, e.g., Page 5, Line 27);

- EP 0, 6559,402 published 28 June 1995 to Indena Sp.a., inventor: Bombardelli et al.

  Bombardelli et al., teach compositions comprising lycopene, β- carotene and procyanidole oligomers, latter extracted from Vitis vinifera, but not glycosaminoglycan and application of said compositions for stimulation or promotion of collagen maintenance and synthesis;

- U.S. Patent 5,906,811 issued 25 May 1999 to Hersh.

  Hersh teaches compositions to prevent and ameliorate symptoms and complications resulting from free radicals mediated damage to oro-phryngeal cavity and mouth. Furthermore, Hersh's

composition while comprising acerola, β- carotene and proanthocyanidines from grape seeds; does not contain glycosaminoglycan.

Thus, the combined teachings from Kosbab, Bombardelli et al., and Hersh; either alone or in combination do not teach a composition comprising instantly claimed ingredients to stimulate or promote collagen maintenance and synthesis. Consequently, the claimed invention is neither anticipated, nor is obvious over the combined teachings from Kosbab in view of Bombardelli et al., and further in view of Hersh.

14. Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

15. Claims 104-106, 108-115, 117, 120-127 and 129-149 are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dr. Kailash C Srivastava/
Examiner, Art Unit 1657

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14 February 2008

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